

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO:

Wave 5 Cases Identified in Exhibit A
attached hereto

ORDER ADOPTING
MEMORANDUM OPINION AND ORDER
(*Daubert* ruling re: Bruce Rosenzweig, M.D.)

Pending before the court is the defendants' Motion to Exclude Certain General Opinions of Bruce Rosenzweig, M.D. [ECF No. 4374] filed on August 15, 2017. For reasons appearing to the court, the court **ORDERS** that the Memorandum Opinion and Order (*Daubert* Motion re: Bruce Rosenzweig, M.D.) [ECF No. 2668] ("Prior Order") entered on August 26, 2016, as to the Ethicon Wave 1 cases is **ADOPTED** in the Wave 6 cases identified in Exhibit A.¹ The Prior Order is attached hereto as Exhibit B.

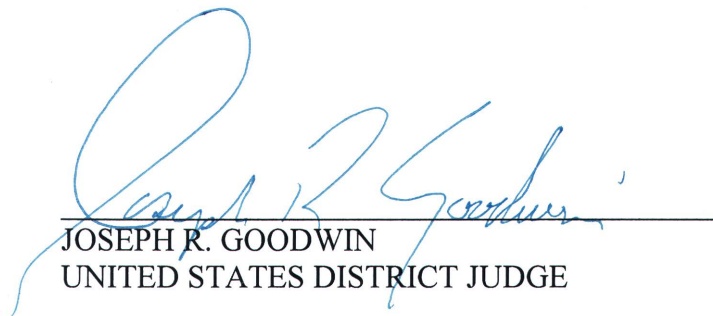
Importantly, the court notes that the expert opinions proffered in Wave 1 are in almost every respect identical to those proffered here. The court has found, however, that with each entered Order, the experts in these cases attempt to bolster or fine-tune the support for their opinions, but the opinions themselves do not change. Accordingly, the court will refrain from engaging in the extremely inefficient practice of continuously reexamining the qualifications, reliability, and relevance of dozens of experts and their

¹ On Exhibit A, I have marked through cases that are closed, on the inactive docket, not in Wave 5, could not be identified because of an error in the style or case number, or assigned to another District Judge.

numerous opinions. While the parties continue to challenge even the slightest alteration to the underlying support for an expert's opinion, the court's review of the parties' arguments reveals that these refreshed *Daubert* challenges are different from previous arguments by only the very slightest of degrees. The court **FINDS** that to the extent that the parties raise arguments not previously addressed by the court's Prior Order, the trial judge may easily resolve these issues at trial without the need for further briefing or an evidentiary hearing. Accordingly, the court **ORDERS** that to the extent that the parties raise *Daubert* challenges not previously addressed in the court's Prior Order—fully adopted herein—those challenges are **RESERVED for trial**.

The court **DIRECTS** the Clerk to file a copy of this Order Adopting Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 5 cases identified in the Exhibit attached hereto.

ENTER: July 27, 2018



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

Case Name	Case Number
Mary J. Abadie	2:12-cv-07356
Lesa Adams	2:12-cv-07658
Margaret Aldridge	2:12-cv-05750
Rita M. & Charles E. Appleton	2:12-cv-07872
Cathy & Peter Balura	2:12-cv-07854
Susan & Ronnie Jerome Bethune	2:12-cv-07852
Patricia & Dale Blake	2:12-cv-07901
Jane & Frederick, III Bordelon	2:12-cv-07431
Celeste P. Bybel	2:12-cv-07495
Sonja & Layn Callahan	2:12-cv-06387
Lisa O. Campbell	2:12-cv-07659
Phyllis Clark	2:12-cv-06481
Paula Carole & Audie L. Pope Clowe	2:12-cv-06893
Ethel Davis	2:12-cv-06388
Sherry P. Deaton	2:12-cv-05774
Raja Dobard	2:12-cv-07493
Virginia L. & Ronald DuBois	2:12-cv-08070
Catherine & Richard Dupont	2:12-cv-07490
Carla & Edward Lester, Jr. Eason	2:12-cv-07909
Lula F. Fender	2:12-cv-06182
Patsy Frame	2:12-cv-07524
Margaret Richard Fremin	2:12-cv-07523

Cherrie Garrison	2:12-cv-06390
Ora Kay & Clarence Allen Gray	2:12-cv-07251
Kassandra & Cody Greenwood	2:12-cv-07889
Sabrina Harris	2:12-cv-07582
Kathleen Heintz	2:12-cv-07579
Laurie & Paul Hoggatt	2:12-cv-05667
Mary & Jimmy Holley	2:12-cv-07750
Dianne Jaufre	2:12-cv-07573
Iris A. & Michael Jennings	2:12-cv-06217
Mary Alice & Nolan, Jr. Landeche	2:12-cv-07962
Sherrie Leith	2:12-cv-08079
Maria Lockwood	2:12-cv-07649
Linda A. & Henry Martin	2:12-cv-07853
Clarisa McCoy	2:12-cv-07646
Betty Linton McCumber	2:12-cv-08083
Jamie & Travis McLain	2:12-cv-08004
Rosario Mendiola	2:12-cv-07805
Joycelyn Miller	2:12-cv-07644
Gwendolyn C. Mixon	2:12-cv-07143
Ella Morrison	2:12-cv-07935
Betty Nethercott	2:12-cv-05802
Teresa Palmer	2:12-cv-07902
Tamara & John Pavlekovich	2:12-cv-06772
Teresa L. Phelps	2:12-cv-05790

Robin Prestage	2:12-cv-07936
Judy & Brian E. Rayburn	2:12-cv-07711
Virginia & Richard Reeves	2:12-cv-06408
Veronica A. Ross	2:12-cv-07419
Santa Santana	2:12-cv-07849
Genevieve S. Schwartz	2:12-cv-06184
Teresa & Giuseppe Sciumbata	2:12-cv-07037
Cassandra Scott	2:12-cv-07846
Tammy Surcey	2:12-cv-05668
Bessie & William, Sr. Taylor	2:12-cv-07784
Shirley Terrebonne	2:12-cv-07779
Anna M. Thompson	2:12-cv-06179
Loral Tichbourn	2:12-cv-07777
Jodi & Leffy Valverde	2:12-cv-07999
Yadira & Ricardo Vazquez	2:12-cv-07840
Karen & Victor E. Weaver	2:12-cv-07769
Stephanie & Larry Wells	2:12-cv-06438
Patricia Wilcher	2:12-cv-06573

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Bruce Rosenzweig, M.D.)

Pending before the court is the Motion to Exclude Certain Opinions of Bruce Rosenzweig, M.D. [ECF No. 2047] filed by the defendants Ethicon, Inc. and Johnson & Johnson (collectively “Ethicon”). The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.¹

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties’ misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*’s core considerations for assessing expert

¹ Ethicon identified the Wave 1 cases affected by this Motion in its attached Exhibit A [ECF No. 2047-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert

testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of “junk science” looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court’s prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these

standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Rosenzweig is a pelvic surgeon and urogynecologist. Ethicon seeks exclusion of his expert testimony on several grounds.

a. Alternative Design

First, Ethicon argues that Dr. Rosenzweig should not be permitted to testify that alternative procedures are safer than Ethicon's mesh products. Ethicon does not challenge Dr. Rosenzweig's qualifications or the reliability of this expert testimony; instead, Ethicon challenges the relevance of this expert testimony. The relevance of this expert testimony is better decided on a case-by-case basis. Accordingly, I **RESERVE** ruling until trial.

Next, Ethicon claims Dr. Rosenzweig is not qualified to offer expert testimony on whether there are clinical differences between mechanical-cut and laser-cut mesh products. According to Ethicon, Dr. Rosenzweig cannot offer expert testimony on this issue because he is not specially trained in product design processes. However, I find that a urogynecologist who has extensive experience working with mechanical-cut and laser-cut mesh products—like Dr. Rosenzweig—is qualified to offer expert testimony of this sort. The plaintiffs' Motion is **DENIED** on this point.

Third, Ethicon challenges the reliability of Dr. Rosenzweig's expert testimony about mechanical-cut and laser-cut mesh. Faced with this challenge, the plaintiffs retort that Dr. Rosenzweig's clinical experience provides a reliable foundation for this expert testimony.

In the abstract, experience—on its own or accompanied by little else—is a reliable basis for expert testimony. *See Kumho*, 526 U.S. at 156. But the reliability inquiry must probe into the relationship between the experience and the expert testimony:

If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.

Fed. R. Evid. 702 advisory committee's note to 2000 amendment. Here, the court does not have enough information to judge the reliability or relevance of Dr. Rosenzweig's particular experience.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on whether mechanical-cut mesh is safer than laser-cut mesh based primarily on an expert's clinical experiences. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

Finally, Ethicon challenges the reliability of Dr. Rosenzweig's expert testimony about Ultrapro mesh as an alternative. Ethicon first argues that this testimony is based on a logical fallacy—the logical fallacy being that a device that results in fewer complications is a safer alternative design. I see no logical fallacy here; whether an alternative device has few complications is surely related to whether the alternative is safer. Ethicon then argues that Dr. Rosenzweig cannot claim Ethicon had insufficient long-term studies about its mesh products and then offer up an alternative (i.e., Ultrapro) that was the subject of a single study and that Dr. Rosenzweig believes should be studied longer. I am not convinced these facts render Dr. Rosenzweig's expert testimony unreliable, especially considering his reliance on other studies that he explains are relevant to this expert testimony. While Ethicon may explore its concerns on cross-examination,

its Motion is **DENIED** on this point.

b. Warnings

Ethicon asks the court to exclude Dr. Rosenzweig’s expert testimony about whether the relevant Instructions for Use adequately warned about the duration, severity, and frequency of risks. Ethicon does not claim Dr. Rosenzweig is unqualified or offers expert testimony that is unreliable.² It appears Ethicon’s argument centers on the relevance of this expert testimony. In Ethicon’s opinion, a manufacturer does not have a legal obligation to warn about the duration, severity, and frequency of risks, so these matters do not bear on whether Ethicon provided adequate warnings. I disagree; as do other courts. *E.g.*, *Cisson v. C. R. Bard Inc.*, No. 2:11-cv-195, 2013 WL 5700513, at *7 (joining other courts in finding “a failure to warn about the rate or severity of potential injury creates a jury question over the adequacy of warnings.”). Accordingly, Ethicon’s Motion is **DENIED** on this point.

c. Properties

Ethicon seeks to preclude Dr. Rosenzweig from testifying about degradation and other biomaterials opinions—specifically his opinions that Ethicon’s mesh devices degrade, are subject to fraying and particle loss, and are cytotoxic. Ethicon objects to Dr. Rosenzweig’s testimony on these subjects because he cannot connect the alleged phenomena to “adverse events experienced by women.” Mem. 12–13 [ECF No. 2049]. I reject this argument. A single expert need not provide all the pieces of

² In its reply brief—and in the briefest fashion—Ethicon claims Dr. Rosenzweig is not qualified to offer this expert testimony. I decline to decide a matter raised in such short order, especially when raised in a reply brief and without affording the plaintiffs an opportunity to respond.

the puzzle for their testimony to be useful to the jury in determining the ultimate issues in the case. *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710 (S.D. W. Va. 2014) (rejecting a similar argument). Dr. Rosenzweig’s testimony is a relevant step towards establishing general causation. Nor does his alleged inability to connect degradation, fraying, particle loss, and cytotoxicity to specific complications undermine the reliability of his testimony that these phenomena occur. Ethicon’s Motion is **DENIED** on these matters.

d. MSDS

Ethicon seeks to preclude Dr. Rosenzweig from using the MSDS—specifically the MSDS statement that polypropylene is incompatible with strong oxidizers—as the basis for his opinion that the mesh at issue should not be used in the vagina.

First, Ethicon argues that the MSDS “provides no support for the opinions expressed,” because the MSDS “does *not* forbid implantation in humans.” Mem. 14 [ECF No. 2049] Additionally, Ethicon states that the MSDS is for “‘polypropylene resin,’ not polypropylene and certainly not Prolene.” *Id.* I find these concerns without merit. The MSDS need not expressly forbid implantation in humans for Dr. Rosenzweig to use its statements about strong oxidizers—which he explains are readily found in the vagina—to support his concerns about mesh use in the vagina. To the extent Ethicon disagrees with Dr. Rosenzweig’s conclusion, Ethicon’s objections are better suited for cross-examination. Ethicon’s Motion on this point is **DENIED**.

Ethicon also argues that Dr. Rosenzweig is unqualified to offer opinions based

on the MSDS because Dr. Rosenzweig does not know how the MSDS was prepared. I disagree. A urogynecologist does not need to be an expert in crafting MSDS warnings to use the substance of such warnings in forming opinions about how mesh reacts in the human body. Accordingly, Ethicon's Motion is **DENIED** on this point.

e. Complications

Ethicon moves for the exclusion of Dr. Rosenzweig's opinions relating to his allegations that TVT causes cytotoxicity and that Ethicon should have warned physicians of that fact. Additionally, Ethicon argues that Dr. Rosenzweig is not qualified to offer opinions regarding the adequacy of Ethicon's testing regarding cytotoxicity.

The plaintiffs point out that this court previously ruled on this issue in *Huskey*, 29 F. Supp. 3d 691, and the court permitted Dr. Rosenzweig's opinions regarding cytotoxicity. The court's former determination was based on Dr. Rosenzweig's extensive interaction with patients exhibiting complications, surgeries that he has performed, and internal Ethicon studies and documentation showing TVT-O could cause cytotoxicity. *Huskey*, 29 F. Supp. 3d at 705. Dr. Rosenzweig's qualifications are the same in this case. To the extent that Ethicon believes cytotoxicity is not clinically significant, Ethicon may cross-examine Dr. Rosenzweig on that issue. Accordingly, Ethicon's Motion regarding Dr. Rosenzweig's opinions relating to cytotoxicity is **DENIED**.

However, I **FIND** that Dr. Rosenzweig is not qualified to opine that Ethicon's testing was insufficient. There is no indication that Dr. Rosenzweig has any

experience or knowledge on the appropriate testing a medical device manufacturer should undertake. Therefore, Dr. Rosenzweig's testimony that Ethicon failed to appropriately test for cytotoxicity is **EXCLUDED**.

Ethicon next argues that Dr. Rosenzweig's opinion that the shorter length of laser-cut mesh in the TVT Abbrevio leads to more complications should be excluded as unreliable. Dr. Rosenzweig does not cite to any study or personal experience to support his opinion, but he instead cited to an internal Ethicon document that does not support his opinion. Dr. Rosenzweig simply provides no reliable methodology for his opinions regarding laser-cut mesh. These opinions are **EXCLUDED**.

f. Design Process

Ethicon claims Dr. Rosenzweig is not qualified to offer what it characterizes as design opinions. But they do not explain or identify design opinions with sufficient specificity. This most recent wave of *Daubert* motions in this MDL is plagued with some confusion about what constitutes a design opinion. So some clarification is necessary before proceeding.

At first glance, it seems Ethicon wants to prevent Dr. Rosenzweig from providing any opinions that even mention the word "design." But the mere utterance of a single word is not some incantation that transforms an opinion about one thing into something else.

A close, contextual reading of the transvaginal mesh cases where this issue has been raised before reveals the heart of Ethicon's objections. In this motion—and several others—the plaintiffs argue that the expert at issue lacks the particularized

skill, knowledge, experience, education, or training that is necessary to provide opinions about the process of designing a product. Opinions of this sort include, for example, opinions about pre-marketing product testing and product development.

Suffice it to say, an expert opining on these matters must possess skills, knowledge, experience, education, or training particularly relevant to the processes at issue. *See, e.g., Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 550 (S.D. W. Va. 2014) (finding expert who “participated in the development of mesh products” qualified to discuss design procedure). Experience as a practicing urogynecologist or urologist alone does not translate into experience with or knowledge about the process of designing a product.

Ethicon claims Dr. Rosenzweig is not qualified to opine on the design of the relevant mesh products because he does not have any experience with biomaterials or polymer chemistry and because he has not conducted comparative mesh studies. But Dr. Rosenzweig is familiar with the design of surgical products. For example, he has invented a catheter device. In short, this experience combined with surgical experiences makes Dr. Rosenzweig is qualified to provide opinions of this sort.

Furthermore, contrary to Ethicon’s contentions, Dr. Rosenzweig has a reliable basis for his design opinions. He considered more than internal corporate documents in arriving at his opinion on the design of the relevant products; he relied on his experience and relevant scientific literature. His detailed examination of the literature in light of his firsthand experience with mesh devices satisfies the

reliability requirements of *Daubert*. Accordingly, Ethicon's Motion is **DENIED** on this very limited issue.

g. Marketing

Ethicon seeks to exclude Dr. Rosenzweig's expert testimony about whether its products were less effective or less safe for certain patient populations. In the past, I have excluded this testimony because "it is not helpful to the jury to have Dr. Rosenzweig read a document explaining what the inventor of the [product] thought about this. The jury is capable of reading that document itself." *Edwards v. Ethicon, Inc.*, 2:12-cv-9972, 2014 WL 3361923, at *10 (S.D. W. Va. July 8, 2014). I see no reason—nor have I been given one—to depart from this conclusion. Accordingly, Dr. Rosenzweig's expert testimony on this matter is **EXCLUDED**.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913,

921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 (“[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.”). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors “to erroneously conclude that regulatory compliance proved safety.” *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon’s compliance with or violation of the FDA’s labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon’s compliance with design control and risk management standards. Some of this testimony involves the FDA’s quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and

international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at

a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury’s fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g., United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (“[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (“Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.”). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “unreasonably dangerous,” or “proximate cause.” *See Perez v. Townsend Eng’g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit

for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

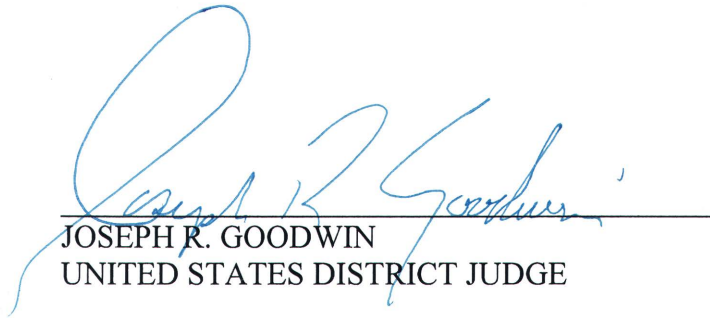
Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be exclude, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part**, **GRANTS in part**, and **RESERVES in part** the Motion to Exclude Certain Opinions of Bruce Rosenzweig, M.D. [ECF No. 2047].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: August 26, 2016



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE